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May 19, 2015

The Honorable Fred Upton

Chairman

House Energy & Commerce Committee

The Honorable Frank Pallone

Ranking Member

House Energy & Commerce Committee

Dear Chairman Upton and Ranking Member Pallone,

On behalf of the Advanced Medical Technology Association (AdvaMed) and the nearly two million men and women whose jobs are supported by the medical technology industry, I am writing to express our support for the 21st Century Cures Act. Our industry shares your goal of accelerating the discovery, development and delivery of cures for patients, and believes that your legislation holds the promise to strengthen the American innovation ecosystem.

The medical technology industry is central to the development of technologies and diagnostics that will provide the life-saving and life-enhancing treatments of the future. Patient access to advanced medical technology generates efficiencies and cost savings for the health care system, and improves the quality of patient care. Between 1980 and 2010, advanced medical technology helped cut the number of days people spent in hospitals by more than half and add five years to U.S. life expectancy while reducing fatalities from heart disease and stroke by more than half.

The impact of medical technology on economic growth and competitiveness goes well beyond the jobs and economic activity associated with industry R&D and manufacturing. A recent study by the Milken Foundation examined four diseases and a limited number of technologies used to treat those diseases. It found significant increases in labor force participation and productivity directly attributable to the technologies' contribution to reducing the burden of illness. The study showed billions of dollars in expanded GDP as a result of treating these four disease states alone.

While the gains in health over recent decades have been impressive, past progress pales compared to future opportunities. In this century of the life sciences, technological advances driven by fundamental advances in knowledge of human biology and continued progress in computing, communications, materials science, physics and engineering can be expected to fuel creation of new and better medical technology products—if there is a sound innovation ecosystem supporting not only continued scientific progress but the translation of scientific advances into better health.

But the innovation ecosystem that supports our industry is severely stressed. Venture capital flowing to the medical device sector is both an essential generator of future



progress and an index of the attractiveness of investing in the development of new treatments and cures. Many of the true breakthrough therapies and diagnostics in the medical technology industry flow from venture funded start-ups. Venture investment in medical technology declined by 42 percent between 2007 and 2013. Even more ominous is the decline in investment for start-up companies at the earliest stage — the seed corn for the next generation of treatments and cures. First time funding for medical technology start-ups dropped by almost three-quarters over the same period.

Policy improvements are essential if America is to retain its world leadership and the potential for medical progress in this century of the life sciences is to be fulfilled. The 21st Century Cures Act includes a number of proposals designed to strengthen the innovation ecosystem and support the development of life-saving, life-enhancing medical technology. This includes key improvements to FDA's premarket program for medical devices – most significantly the establishment of an expedited pathway for breakthrough, innovative technologies – which will increase the efficiency, predictability and transparency of the agency's review process and improve patient access to the best in medical progress. The bill also provides increased NIH funding which will help strengthen our R&D infrastructure.

These provisions are an important and significant first step to strengthen our innovation ecosystem. We understand that the committee is still working to address additional items that may be added to offset the budgetary implications of the legislation. We look forward to reviewing these additions and evaluating their impact on our perspective on the legislation.

We support your legislative efforts, and look forward to working with the committee as the 21st Century Cures Act moves forward. We also look forward to further dialogue on how we can address other weak points in the innovation ecosystem, including the Medicare coverage delays and payment challenges that are discouraging investment in new medical innovations.

Thank you for your efforts to encourage innovation in medical technology.

Sincerely,

Stephen J. Ubl
President and CEO

AdvaMed

Cc: Members of the House Energy & Commerce Committee